# 510(k) Summary

NOV 19 2004

Submitter: iCAD, Inc.
2689 Commons Blvd., Suite 100
Beavercreek, OH 45431

Contact Person: John Rosenstengel

Date Prepared: November 18, 2004

Device Trade Name: Second Look® Viewer

Common Name: System, Image Processing, Radiological

Classification Name: Picture archiving and communications system (21 CFR 892.2050)

Predicate Device(s): Consultiva™ Report Station (RS) by MiraMedica, Inc.

Device Description: The Second Look® Viewer is composed of three primary components. The major component is the computer (1), which is supported by a touchscreen monitor (2) and a barcode reader (3). The computer is a conventional Intel based computer that is connected to the Second Look® CAD processing unit via a network. The Second Look Viewer serves no other purpose than viewer support. The physician interfaces to the software using the touch screen or barcode reader. The physician first barcodes a given patient whose mammography case has already been processed by the Second Look CAD processing unit. The viewer displays the Mammagraph™s with the pre-computed CAD marks overlayed. Second Look Viewer allows a radiologist to review Second Look® Analog CAD output, in softcopy format. The physician may touch any of the small images and see a higher resolution, magnified image along with characterization information for that image. After viewing the mammography case, the radiologist may use the Second Look® Viewer to review pre-computed ultrasound results, such as CADStream® output, if such results already exist for the case under review.

Indication for Use: The Second Look® Viewer is intended to be used to display low resolution, nondiagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks.

Technological Characteristics and Testing:

Conclusion:
Results of performance and validation testing indicate that the Second Look® Viewer is substantially equivalent to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

Mr. John E. Rosenstengel
Director, Quality &
Regulatory Affairs
ICAD, Inc.
2689 Commons Blvd., Suite 100
BEAVERCREEK OH 45431

Re: K042697
Trade/Device Name: Second Look® Viewer
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 30, 2004
Received: September 30, 2004

Dear Mr. Rosenstengel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042697

Device Name: Second Look® Viewer

Indications for Use:

The Second Look® Viewer is intended to be used to display low resolution, nondiagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks.

Prescription Use__X__ ~~AND~~/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Part C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042697